In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: October 29, 2015)

BERNARD HALVERSON, Executor of the Estate of SUSAN HALVERSON, Deceased,	*	PUBLISHED
Petitioner,	*	No. 15-227V
v.	*	Special Master Roth
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Influenza Vaccine; Flu Vaccine; Fluzone Vaccine; Sanofi Pasteur; Denying Subpoena
Respondent.	*	

Jerry A. Lindheim, Locks Law Firm, Philadelphia, PA, for petitioner.
Lisa A. Watts, United States Department of Justice, Washington, DC, for respondent.

ORDER DENYING SUBPOENA[1]

Bernard Halverson ("petitioner"), acting as the representative of the estate of Susan Halverson, claims the Fluzone vaccine caused Ms. Halverson's death and seeks compensation pursuant to the National Vaccine Injury Compensation Program ("the Program").[2] On August 27, 2015, petitioner requested information from Sanofi Pasteur, which manufactures and markets the Fluzone vaccine. Sanofi Pasteur objects to providing the requested information. For the reasons explained below, petitioner did not meet the standard for discovery in the Vaccine Program. Thus, petitioner's motion to subpoena Sanofi Pasteur is DENIED.

[1] The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that this order be publicly available. In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the identified material fits within this definition, such material will be redacted from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 *et seq*. (hereinafter "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

I. Facts and Procedural History

The relevant facts about Ms. Halverson to this issue are relatively few. For this reason and because cases in the Vaccine Program are closed, *see* 42 U.S.C. § 300aa-12(d)(4), the facts are presented summarily.

Ms. Halverson, then age 65 received the Fluzone vaccine on January 9, 2014. Petitioner's Exhibit (Pet. Ex.) 3, p. 4 (vaccination record). On January 13, 2014, Ms. Halverson collapsed at home and subsequently died of cardiac arrest on that date. Pet. Ex. 9 (records of Shore Medical Center); Pet. Ex. 2 (Death Certificate).

On March 4, 2015, Mr. Bernard Halverson filed a petition seeking compensation as the executor of Ms. Halverson's estate.

On July 17, 2015, respondent filed its Rule 4(c) report concluding that the petitioner had failed to meet to his burden of proof in this matter for lack of causation evidence. (ECF No. 13).

On August 12, 2015, petitioner requested that respondent provide any documents relied upon in the Rule 4(c) report but was informed that there were none. Motion To Obtain Order For Issuance Of Subpoena To Non-Party Manufacturer Pursuant To Rule 7(c) Of The Vaccine Rules ("Pet'r Mot. for Subpoena") at 3.

On August 17, 2015, petitioner contacted the manufacturer of the vaccine and requested that the company willingly provide documentation regarding the vaccine. On August 24, 2015, the non party manufacturer declined to comply with the petitioner's request. Pet'r Mot. for Subpoena, filed Aug. 27, 2015, at 3.

On August 20, 2015, petitioner submitted a FOIA request to the United States Food and Drug Administration (FDA), who is currently reviewing his request related to the toxicity and adverse effects of the Fluzone vaccine. Pet'r Mot.for Subpoena at 3.

On August 27, 2015, petitioner filed Pet'r Mot. for Subpoena. The same day, petitioner also filed "Petitioner's Memorandum of Law in Support of the Motion To Obtain Order For Issuance Of Subpoena To Non-Party Manufacturer Pursuant To Rule 7(c) Of The Vaccine Rules" ("Pet'r Mem.").

Petitioner submits that his expert, Dr. Stewart Ehrreich, requires the information that is the subject of petitioner's Subpoena "in order to conduct a comprehensive assessment of the issues in this matter." Pet'r Mem. at 7. Petitioner likewise submits that the documentation is necessary for petitioner's ability to present "the strongest causation evidence in this matter. " *Id.* at 7. However, petitioner states as follows:

> Dr. Ehrreich has concluded to a reasonable degree of professional certainty, that Petitioner's claim is supported by scientific evidence. The evidence demonstrates a causative link between the administration of the vaccine and adverse cardiac events… Petitioner's expert opines that the vaccine can cause adverse

> effects with respect to the rate and/or rhythm of the heart, which can lead to cardiac arrest and death.

Id. at 9 (referencing Ex. D). Respondent submits that she has no *per se* objection to petitioner's request to subpoena documents from Sanofi Pastuer, but notes that "the extensive information sought from the vaccine manufacturer is not *necessary* for the petitioner to go forward in this case with the opinion of Dr.Erreich and/or Dr. Stark (petitioner's other expert)." Respondent's Response ("Res. Resp.") at 2, 4-5 (citing Pet'r Mot. for Subpoena at ¶3). Respondent further states that "it is neither reasonable nor necessary for Dr. Erreich to perform his own study to provide an opinion in this case." Res. Resp. at 5.

II. Discovery in the Vaccine Program

Discovery is not a matter of right in the Vaccine Program. 42 U.S.C. § 300aa–12(d)(3) ("[t]here may be no discovery in a proceeding on a petition other than the discovery required by the special master").

The statutory standard set forth by the Vaccine Program and the inquiry the Special Master must make is whether the information sought in discovery is "reasonable and necessary." Reasonable and necessary has been interpreted to mean that discovery is appropriate when:

> the special master concludes that, given the overall context of the factual issues to be decided by the master, he or she could not make a *fair and well-informed* ruling on those factual issues without the requested material. Requiring the requested testimony or document production must also be 'reasonable' under all the circumstances, which means that the special master must consider the *burden* on the party who would be required to testify or produce documents.

In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Master Autism File, 2004 WL 1660351, at *9 (Fed. Cl. Spec. Mstr. July 16, 2004)[3] (italics added).

Special masters have generally refrained from ordering discovery in a variety of contexts. *See In Re: Omnibus Autism Proceeding*, Master Autism File, 2007 WL 1983780 (Fed. Cl. Spec. Mstr. May 25, 2007) (three special masters declined to order production of information from the Vaccine Safety Data project held by an insurance company); *Werderitsh v. Sec'y of Health & Human Servs.*, No. 99–319V, 2005 WL 3320041 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (special master denied petitioner's request for access to information from Vaccine Adverse Event Reporting System), compensation granted, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. March 30, 2006); *Schneider v. Sec'y of Health & Human Servs.*, No. 99–0160V, 2005 WL 318697, at *5 (Fed. Cl. Spec. Mstr. Feb. 1, 2005) (special master denied request for access to information about manufacturing and testing hepatitis B vaccine from manufacturer), *aff'd*, 64 Fed. Cl. 742, 745-46 (2005); *Phillips-Deloatch v. Sec'y of Health & Human Servs.*, No. 09-171V, 2015 WL 1950107

[3] This case describes discovery in the Vaccine Program thoroughly.

(Fed. Cl. Spec. Mstr. April 9, 2015) (special master denied request for access to information about manufacturing and testing Gardasil vaccine from manufacturer, holding mere possibility that information in vaccine manufacturer's possession might provide clue as to what had caused death was insufficient to satisfy the "reasonable and necessary" standard for granting of discovery from manufacturer in connection with petition filed under the National Childhood Vaccine Injury Act); *See* H.R. Rept. No. 99-908, at 6-7 (1986) *reprinted in* 1986 U.S.C.C.A.N. 6345-47; *see also In re Claims*, 2004 WL 1660351, at *5-6 (discussing discovery sought from vaccine manufacturers).

That being said, vaccine manufacturers are not exempt from discovery in the Vaccine Program: "[T]he statutory language plainly does not exempt anyone from being potentially required to provide testimony or documents, stating that a special master may 'require the testimony of any person and the production of any documents.' " Omnibus Autism Proceeding, 2004 WL 1660351, at *6 (quoting 42 U.S.C. § 300aa–12(b)(3)(B)(ii)). The only exclusion that Congress provided included "Trade Secret(s) or commercial or financial information." *Id.* (quoting 42 U.S.C. § 300aa–12(d)(4)(B)). This suggests that where appropriate, a vaccine manufacturer would be required to produce documentation in a vaccine claim.

In conclusion, the inquiry is whether the information being requested by petitioner is "reasonable and necessary" for the Special Master to make a "fair and well informed decision" concerning whether the Fluzone vaccine administered to Mrs. Halverson caused her death.

III. Analysis

The vaccine at issue is the High Dose Fluzone Vaccine manufactured by Sanofi Pasteur.

Petitioner submits that he has retained two experts in this matter, Dr. Stewart Ehrreich, a pharmacology expert, who will provide a medical theory connecting the vaccination and the injury, and Dr. Robert Stark, a cardiologist who will opine on causation based upon the decedent's medical history and administration of the vaccine. Pet'r Mot. for Subpoena at 2.

Petitioner submits that Dr. Ehrreich "is able to present a 'persuasive medical theory' at this time", but suggests that "the persuasiveness and weight of this opinion is greatly hindered by the expert's inability to conduct a comprehensive analysis of the issue in this claim." Pet'r Mot. Subpoena at 10; *See* Petitioner's Reply to Respondent's Response to Petitioner's Motion To Obtain Order For Issuance Of Subpoena To Non-Party Manufacturer Pursuant To Rule 7(c) Of The Vaccine Rules ("Pet'r Reply") at 4.

Therefore, petitioner states that the requested information, "including human and animal data, dose-response curves, and adverse events are necessary for petitioner's ability to present the strongest causation evidence in this matter." Pet'r Reply at 3.

A FOIA request made by the petitioner is currently pending before the FDA. *Id.*; Pet'r Reply at 4-5. It is expected that the FOIA request would yield the documentation sought by the petitioner.

Petitioner's burden is to show by preponderant evidence "(1) a medical theory causally connecting the vaccination and the injury: (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *See Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Succinctly, petitioner's burden is a preponderance of the evidence standard, not scientific certainty. According to the petitioner, he already has the scientific evidence sufficient to support his claims

In light of the foregoing and the fact that petitioner already has two expert reports that support his claim, the extensive information sought from Sanofi Pasteur is not necessary to go forward in this case. The results of the FOIA request is as yet unknown as well.

IV. Conclusion

For the reasons explained above, the record does not contain persuasive grounds for requiring production of information from Sanofi Pasteur at this time. Thus, petitioner's motion for subpoena is DENIED. If the time should come where Mr. Halverson does require additional information, he may renew his request for discovery. *See In re Claims*, 2004 WL 1660351, at *16 (declining to impose a deadline for requesting discovery from manufacturers). The Clerk's Office is instructed to provide a copy of this decision to Sanofi Pasteur.

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master